IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Philip KUSK Confirmation No.: 4096

Serial No.: 09/889,491 Art Unit: 1634

Filed: February 5, 2002 Examiner: Juliet Caroline SWITZER

For: GENETIC PREDISPOSITION Attorney Docket No: 8969-029-999

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

This is in response to the Office Action dated May 20, 2003, in which the above-captioned application was examined for restriction purposes only. A Petition for Extension of Time with provision for the required fee is filed concurrently herewith.

On pages 2-3 of the Office Action, it is alleged that the claims encompass seven distinct inventions. In order to be fully responsive, Applicant elects Group 1 (claims 1-15), and selects the combination of the bone sialoprotein gene and the allelic variations BSP-A1496G. However, Applicant respectfully traverses the rejection for the following reasons.

First, Applicant submits that the restriction of the claims is inappropriate in view of the fact that no objection of lack of unity was raised during the international phase of this application. The Examiner's attention is directed to the International Preliminary Examination Report dated September 4, 2001 ("IPER").

Applicant further submits that WO 97/28280 to Grainger *et al.* ("Grainger") provides nothing that contradicts the European Patent Office's conclusion, evidenced in the IPER, that the claims do not lack unity.¹ In particular, the various genetic polymorphisms recited by claim 1 are linked by a common factor inventively differentiating all of them from the polymorphism described in Grainger. All of the proteins coded by the genes recited by

¹ Applicant also disagrees with the allegation, made on page 3 of the Office Action, that the methods recited by the claims do "not provide a special technical feature over the prior art." Indeed, while Grainger alleges that it encompasses "therapies against cancer and auto-immune disorders, based upon identification of a TGF- β 1 polymorphism correlated with a predisposition to these diseases," it provides no information about how such a correlation can be made. Grainger, pp. 7-8. In short, Grainger does not provide an enabling disclosure of the general method it suggests, much less Applicant's invention.

claim 1 have special and specific reference to bone. See, e.g., Specification, page 10. In contrast, TGF- β 1 reportedly correlates to numerous non-bone related and non-calcification related disorders. Grainger, page 1. Accordingly, the methods and combinations within the scope of Applicant's claims are joined not only by the fact that they are methods for assessing an individual's predisposition to a selected calcification condition status by genotyping the promoter of at least one gene, but by the further feature that the gene to which the promoter belongs is a gene relating to a protein which has a high level of specificity to bone.

Second, Applicant respectfully submits that an examination of all of the pending claims would not pose a significant burden. This is evidenced by the fact that searches have already been conducted by the European Patent Office in connection with all of the claims. As the Examiner is well aware, "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." *Manual of Patent Examining Procedure* § 803 (8th ed. August 2001). Therefore, even if the claims did encompass more than one invention, Applicant submits that a requirement that they be examined in separate applications, which would impose upon Applicant significant costs, is inappropriate.²

In sum, Applicant respectfully requests that the restriction requirement be withdrawn. At the very least, however, Applicant respectfully requests that Groups 1, 6 and 7 be examined together.

No fees are believed due for this submission. If any fees are due, however, please charge such fees to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

Date: September 22, 2003

Reg. No. 31,231

For: Victor N. Balancia
PENNIE & EDMONDS LLP

1667 K Street, N.W.

Washington, D.C. 20006

(202) 496- 4400

² Applicant further submits that an election of species should not be required as to individual polymorphisms within a single specific gene promoter, since a search of all such species would pose little difficulty.